



Micro-Star International Co., Ltd.  
Pre-market Notification for E3-80 Portable ECG Recorder

K071085

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### E3-80 Portable ECG Recorder

OCT 3<sup>rd</sup> 2007

### 510(k) Summary of Safety and Effectiveness

#### 1. Submitter

Micro-Star International Co., Ltd.  
No. 69, Li-De Street, Jung-He City  
Taipei Hsien, 235 Taiwan (ROC)

Contact: Album D. Tsai, Regulatory Affairs Representative  
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#### 2. Name of Device

Trade Name: E3-80 Portable ECG Recorder  
Common/Usual Name: ECG Recorder  
Classification: 21CFR 870.2800  
Product Code: Medical Magnetic Tape Recorder  
MWJ  
Electrocardiograph, Ambulatory (Without Analysis)

#### 3. Predicate Device

<u>Trade Name</u>	<u>510(k) Number</u>	<u>Decision Date</u>
Braemar DigiTrak Plus Holter Recorder	K993617	11/24/1999
Del Mar Lifecard CF Compact Holter Recorder	K001025	04/19/2000

#### 4. Device Description

The E3-80 ECG device is designed to be a portable recorder of electrocardiograms. The device has a storage function in which the recorded signals are automatically stored in a removable storage disc for trained healthcare practitioners to perform further analysis using PC-based software.

## 5. Indications for Use

The E3-80 device is a 3-channel portable ECG device designed to record up to 24 hours of ECG signal from the chest surface of adult patients in an ambulatory environment.

The device stores ECG data to a removable storage disc for qualified healthcare providers to perform further analysis of recorded ECG.

## 6. Technological Characteristics

The E3-80 ECG device is a light-weight, pocket-size portable recorder of three channel electrocardiograms. The device has adequate battery life and recording capability for continuous recording of the ambulatory ECG signals for up to 24 hours. The recorded signals are automatically stored in a removable Secure Digital (SD) disc for trained healthcare practitioners to perform further analysis using PC-based software.

## 7. Performance Summary

Various bench and user preference tests were performed to ensure that the E3-80 Portable ECG Recorder meets all functional, performance, and stability requirements for its intended use. The electrical safety and EMC requirements were tested by independent labs in accordance with the requirements specified in IEC 60601-1 and IEC 60601-1-2. Biocompatibility of the electrodes were tested according to ISO 10993 guidelines for “short-term exposure, skin contact devices”.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Micro-Star International Co., LTD.  
c/o Mr. Album Tsai  
Research Center  
No. 69, Li-De Street  
Jung-He City, Taipei Hsien 235  
Taiwan (R.O.C.)

OCT 3 2007

Re: K071085

Trade/Device Name: E3-80 Portable ECG Recorder & Analyzer  
Regulation Number: 21 CFR 870.2800  
Regulation Name: Medical Magnetic Tape Recorder  
Regulatory Class: Class II  
Product Code: MWJ  
Dated: September 20, 2007  
Received: September 24, 2007

Dear Mr. Album Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, MD  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Number (if known):**

K071085

**Device Name:**

E3-80 Portable ECG Recorder

**Indications For Use:**

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The device stores ECG data to a removable storage disc for qualified healthcare providers to perform further analysis of recorded ECG.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR  
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Bummo  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K071085

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